

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effect of 8 weeks of high-intensity interval training of two Different protocols with high and low volumes on the glycemic indices and lipids profile in men With type 2 diabetes

Protocol summary

Study aim

The aim of this study was comparison of the effects of two types of low and high volumes of HIIT training on glycemic indices and lipid profile of men with type 2 diabetes.

Design

Clinical trial with control group by using pre-test and post-test

Settings and conduct

subjects were used by patients with type 2 diabetes in the diabetes center of Yazd province who volunteered to participate in this study. All subjects completed the PAR-Q questionnaire and medical assessment. After signing the consent inform and examination by physicians also doing exercise test they enter to study. In order to blindness, in this study, samples and recipients were unaware of the differences between the two groups

Participants/Inclusion and exclusion criteria

Subjects: included 30 non-athlete and non-insulin dependent diabetic patients age range from 29 to 46 years old and BMI 20 to 36. The severity of the disease was 135-300 mg / dl, after 2 hours glucose , 200 to 400 mg, and A1c was above of 6.5%. By referring to the diabetes center of Yazd province, 30 patients with type 2 diabetes mellitus were selected as the subjects and were randomly divided to two groups of exercise (20 subjects) and control (10 people), they were examined for history of cardiovascular, respiratory, orthopedic problems and diabetic neuropathy by physicians before interventions.

Intervention groups

high volume of HIIT group and Low volume of HIIT group

Main outcome variables

fb; 2hRR; insulin; HOMA-IR; HbA1c; TG; Col

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180827040887N1**

Registration date: **2019-04-26, 1398/02/06**

Registration timing: **retrospective**

Last update: **2019-04-26, 1398/02/06**

Update count: **0**

Registration date

2019-04-26, 1398/02/06

Registrant information

Name

Hamid Abbasi

Name of organization / entity

Yazd University

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-09-26, 1396/07/04

Expected recruitment end date

2017-11-25, 1396/09/04

Actual recruitment start date

2017-09-26, 1396/07/04

Actual recruitment end date

2017-11-25, 1396/09/04

Trial completion date

2018-06-10, 1397/03/20

Scientific title

Comparison of the effect of 8 weeks of high-intensity interval training of two Different protocols with high and low volumes on the glycemic indices and lipids profile in men With type 2 diabetes

Public title

Investigating the effect of different volumes of HIIT training on the health-related indicators of diabetic patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Type II non-athlete diabetic patient The range of glucose is between 126 and 300 mg/l HbA1C above %6

Exclusion criteria:

Cardiovascular disease Diabetic Nephropathy Respiratory diseases orthopedic problems

Age

From **18 years** old

Gender

Male

Phase

Bioequivalence

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **27**

Actual sample size reached: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples were matched by BMI, then randomly divided into 3 groups: two groups of training and one control group.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the two groups of low volume and high volume of training did not aware of intensity and type of intervention and differences between the groups and they only did their protocol. Clinicians and raters were unaware of the two protocols.

Placebo

Not used

Assignment

Parallel

Other design features

Design different HIIT exercises with different volumes.

The aim of this study was to obtain the lowest exercise duration for improvement in health indicators of type 2 diabetic patients

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Yazd Shahid Sadoghi University of Medical Sciences

Street address

Bahonar Sq., Yazd

City

Yazd

Province

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Postal code

8916978477

Approval date

2017-08-15, 1396/05/24

Ethics committee reference number

IR.SSU.REC.1396.103

Health conditions studied

1

Description of health condition studied

Type 2 Diabetes

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

percent of people with high blood glucos

Timepoint

before and after intervention

Method of measurement

Biosystems kit

2

Description

The level of glycemic indexes (fasting blood glucose, two-hourly glucose, insulin, insulin resistance, HbA1c) and lipid profile (LDL, HDL, TG, TC)

Timepoint

All indices of this study were measured before the intervention and 48 hours after the last training session at the laboratory.

Method of measurement

1. Stationary bicycle of China Classic model of China 2. Chest sensor 610 i polar made in China to measure heart rate while exercising with clock for monitoring 3-glucometer to measure blood glucose before and during exercise 4-Blood pressure apparatus In order to measure the blood pressure before and after training, the balance and height meter of the Balas model was used to measure the height with a precision of 1 cm and a precision of 0.001 kg, making Iran 6-calipers made in Japan to measure fat thickness Subcutaneous fat percentage to determine the percentage of fat 7-Physical Fitness Preparation Questionnaire (PAR_Q) in order to

investigate the history of the disease and the readiness of Retire in exercise program and medical history. The questionnaire consists of 7 questions that have a yes or no answer and yes, even if a question is answered as a positive one, they are referred to the doctor. 8. Computer for information analysis. 9-meter strip with a precision of 1 mm

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 1- Low volume HIIT exercises 2. High volume HIIT exercises

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Diabetes center of Yazd

Full name of responsible person

Nasim Namiranian

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Yazd Diabetes Center

Proportion provided by this source

50

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Yazd University

Full name of responsible person

Hamid Abbasi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Sport Medicine

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Person responsible for updating data**Contact****Name of organization / entity**

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